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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/082,502 | 10/19/2001 | Paul O. Sheppard | 97-11C2 | 4613 |

7590

03/02/2004

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| EXAMINER |
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NICKOL, GARY B

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/082,502 | SHEPPARD ET AL. | |
| | Examiner | Art Unit | |
| | Gary B. Nickol Ph.D. | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/3/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

Re: Sheppard *et al.*

Date of Priority: June 17, 1998 (as applied to SEQ ID NOs: 16-21)

The Amendment filed 12/12/2003 in response to the Office Action of 05/14/2003 is acknowledged and has been entered.

Claims 16-18, and 21-25 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 16-17, and 21-22 remain rejected under 35 U.S.C. 102(a) as being anticipated by Yokoyama-Kobayashi, M. *et al.* (Database GenEmbl, Accession No. AB015631, Submitted June 16, 1998) for the reasons of record in the Action mailed 05-14-2003 (page 6). Applicants argue (Remarks, 11/14/2003) that Yokoyama-Kobayashi merely discloses a cds clone, with no indication as to reading frame, signal sequence or mature polypeptide. Applicants argue that Yokoyama-Kobayashi does not teach a mature, isolated polynucleotide. Further, Yokoyama-Kobayashi does not teach recombinant expression in gastric adenocarcinoma cells using expression vectors. Applicants argue that this reference is merely a database entry which

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specifies that the mRNA was isolated from a human gastric adenocarcinoma cell line. Applicants argue that it does not explicitly teach any expression vectors comprising a promoter, a polynucleotide of the present invention and a transcription terminator. These arguments have been carefully considered but are not found persuasive. As set forth previously, the reference teaches an isolated polynucleotide which encodes a polypeptide selected from the group consisting of SEQ ID NO:17 and 20. The reference further includes recombinant expression in gastric adenocarcinomas cells using expression vectors (pKA1-meta-1) wherein such vectors would inherently support transcription promoters and terminators. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

New Rejections/Objections:

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Both expression vectors in Claims 21 and 22 encode a polypeptide selected from the group consisting of SEQ ID NO:17, SEQ ID NO:19, SEQ ID NO:20, and SEQ ID NO:21.

Claims 16-18, and 21-25 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are not *enabled*, because one of ordinary skill in the art could not make/use the invention with any predictability because it appears that essential material necessary towards the practice of the invention has not been properly disclosed.

In the Office Action mailed (05/14/2003), the specification was objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. see pages 61 and 62). In response (Remarks, 11/25/03), Applicants argue that the hyperlinks on pgs. 61 and 62 were included within the present Specification to assist one of skill in the art in the practice of the present invention. Thus, applicants assert (under MPEP 608.01) that the hyperlinks are a necessary inclusion in the patent application in order to comply with the requirements of 35 U.S.C. 112, first paragraph.

Thus, in view of applicant's admission that the hyperlinks are necessary, said hyperlinks represent the incorporation of essential material. However, the incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

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All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

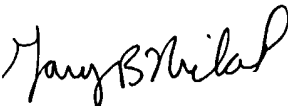
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN


GARY NICKOL
PRIMARY EXAMINER